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Certified Mail
Return Receipt Requested

Roberto Braceras, Esq.
GOODWIN PROCTER LLP
Exchange Place
53 State Street
Boston, Massachusetts 02109

Re: Roy Keim and Doris Keim v. New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center, et al., C.A. No. 1:13-cv-12664-FDS (D. Mass.)

Dear Mr. Braceras:

I represent the plaintiffs, Roy Keim and Doris Keim, in the above-referenced matter. Mr. Keim received an injection of contaminated methylprednisolone acetate (Depo-Medrol) that was compounded by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") at its facilities at 697 Waverly Street in Framingham, Massachusetts. As a direct result of being injected with the contaminated steroid, Mr. Keim suffered from scarring adhesion to the discs located at L4-L5 and L5-S1 and has suffered what is suspected to be permanent nerve injury at the injection site. UniFirst Corporation, through its operating segment or division known as UniClean Cleanroom Services ("UniFirst"), was responsible for cleaning and sanitizing NECC's facilities, but UniFirst failed, *inter alia*, to properly perform those duties and failed to use reasonable care to prevent and eliminate contamination within NECC's facilities. This letter constitutes a demand upon UniFirst pursuant to Massachusetts General Laws, Chapter 93A, § 9 ("Chapter 93A"). Please immediately provide a copy of this letter to UniFirst's insurance carrier.

Relevant Facts

In 2012, Mr. Keim obtained treatment for right lower leg pain at ASC Surgical Ventures, LLC d/b/a O.S.M.C. Outpatient Surgery Center (hereinafter "O.S.M.C.") in Elkhart, Indiana, and on June 29, 2012, Mr. Keim received an epidural injection of methylprednisolone acetate as part of that treatment. The methylprednisolone acetate that was injected into Mr. Keim was compounded and distributed by NECC.

Methylprednisolone acetate is a steroid that is administered via epidural injection to patients suffering from back and/or neck pain. Until October 2012, NECC compounded methylprednisolone acetate at its facility in Framingham, Massachusetts, and NECC

compounded, marketed, sold and distributed tens of thousands of vials of methylprednisolone acetate to healthcare providers across the country.

Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the cleanroom used for the production of methylprednisolone acetate. NECC and UniFirst knew or should have known of these findings. NECC and UniFirst failed to investigate those isolates and made no effort to identify those isolates, and NECC and UniFirst failed to take any corrective actions with regards to the isolates which were found. Despite these findings, NECC continued to compound, market, sell and distribute methylprednisolone acetate.

On September 21, 2012, the Centers for Disease Control and Prevention (the "CDC") was notified by the Tennessee Department of Health of a patient with the onset of meningitis following an epidural steroid injection. It was later determined that the patient had fungal meningitis.

On its website, CDC explains that "fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus[,]" and that "fungal meningitis is rare and usually the result of spread of a fungus through blood to the spinal cord." According to the CDC, symptoms for meningitis include the following: new or worsening headache; fever; sensitivity to light; stiff neck; new weakness or numbness in any part of the body; slurred speech; and increased pain, redness or swelling at the injection site. Death may result from meningitis. The symptoms of fungal meningitis, according to the CDC, "are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might just have one or two of these symptoms."

In late September 2012, NECC recalled the following lots of methylprednisolone acetate (PF) 80mg/ml that it had compounded and sold: Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013. NECC identified O.S.M.C. as one of the healthcare facilities that received vials of methylprednisolone acetate that were part of the September 2012 recall.

On October 6, 2012, NECC announced that it was recalling "all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts." In NECC's October 6, 2012, press release, NECC advised that it was "notifying its customers of this recall by fax[,]" and that "[c]linics, hospitals and healthcare providers that have product which is being recalled should stop using the product immediately, retain and secure the product, and follow instructions contained in the fax notice."

On October 9, 2012, Mr. Keim was advised of the meningitis outbreak. Mr. Keim continued to experience pain with sitting, walking and moving around, and after further injections of Omnipaque contrast and Celestone which did not alleviate his pain, it was recommended that Mr. Keim undergo hemilaminotomies on the right at L4-L5 and L5-S1 and diskectomy on the right at L4-L5 and L5-S1.

Mr. Keim had surgery on November 12, 2012. Following the procedure, the surgeon indicated to Mr. Keim that he had considerable scarring adhesion of the nerve root to the disk, which was not usual, and that a contaminated injection and local infection could certainly have caused the amount of scar tissue that was present and that he suspected that Mr. Keim had some permanent injury to that nerve.

Liability

UniFirst holds itself out as a service provider delivering value-added services and products to, among other industries, the medical device, pharmaceutical, and other industries that utilize cleanroom controlled environments. UniFirst represents that it offers comprehensive cleanroom cleaning and maintenance programs to help ensure that facilities are operating within specified classification goals. UniFirst touts its expertise to companies like NECC.

UniFirst knows that particulates in cleanrooms are deposited onto surfaces such as floors, walls, work surfaces and machinery, and that these particulates may cause increases in manufacturing and product compounding reject rates. UniFirst, its agents, employees, representatives, and UniClean workers have, for many years, had actual knowledge that visible and non-visible particulate loads can also lead to product contamination safety concerns for end users. In its marketing materials UniFirst acknowledges that to reduce these risks, it is imperative that an effective cleanroom cleaning program be implemented and maintained. UniFirst claims to follow stringent cleaning procedures and claims to employ highly-trained technicians as key components in eliminating such contamination threats.

At all times mentioned herein and material hereto, UniFirst held itself and its agents, servants, workers, representatives, personnel, and employees out to be skillful and qualified to deliver quality services and products and through the highest standards. Indeed, UniFirst represents that it is an ISO 9001: 2008 registered company offering services that include sterile and non-sterile garment services, and contamination control including cleanroom cleaning, fogging and environmental monitoring, among other services.

UniFirst recognizes the dangers associated with contaminated cleanrooms. In the company's own marketing materials, it acknowledges that "80% of the dirt and grime that enters your building is tracked in on the shoes of employees and visitors." UniFirst knows that any contract for services or products entered into with any company such as NECC has a direct benefit for customers, who are the intended beneficiaries of such contracts. For example, UniFirst has stated on its website and in marketing materials that over 70% of customers say that a poorly maintained facility "is enough reason not to patronize a business again," and that by hiring UniFirst, a company's "business image will remain spotless, and your customers and employees will know you care."

UniFirst markets its products and services aggressively, and represents that, among other things, "[t]o help with your infection control efforts, UniFirst delivers fresh mops and wipers and picks up your soiled ones on a regular schedule. We maintain inventory, perform hygienic laundering, and replace any worn out items."

UniFirst entered into a Contamination Control Service Agreement ("CCSA") with NECC on October 7, 2008, and renewed it thereafter, such that a contract existed in calendar years 2011 and 2012. According to the terms of the CCSA and later iterations, UniFirst agreed to furnish services with supporting materials necessary for the performance of its duties, which expressly included cleaning each cleanroom at NECC's facilities. UniFirst's duties were outlined in a Service Schedule attached and incorporated into the CCSA first signed and thereafter in force and effect. UniFirst's duties included cleaning and sanitizing each anteroom and cleanroom. The areas to be cleaned and sanitized by UniFirst employees included, but were not limited to, the floors, ceilings, and hoods of each room. UniFirst agreed to a triple decontamination process for each room, using products provided by UniFirst. UniFirst further agreed that, among other things, it would specifically provide its staff with cleanroom training and training regarding NECC's Standard Operating Procedures.

UniFirst performed services and sold products to NECC each month, from calendar year 2010 through September 2012, and UniFirst invoiced NECC for services rendered. During the stated time frame, UniFirst failed to meets its own written standards in performing its contractual duties, allowing the contamination of the cleanrooms UniFirst was entrusted to clean in the following ways: (i) UniFirst employees, contractors and/or representatives, including those within the UniClean division, entered the NECC facilities (including the anterooms) in street clothes, without donning sterile or contaminant-free protection, such as shoe covers, hair caps, coveralls, and gloves that were readily available at the NECC facilities; (ii) UniFirst employees, contractors and/or representatives brought into the NECC anterooms and cleanrooms cleaning equipment, including mops, mop heads, sponges and buckets that had been moved through exterior environments, even though such equipment had not been sanitized by or cleaned appropriately, allowing contamination to occur throughout various parts of NECC's facilities; and (iii) UniFirst employees, contractors and/or representatives failed to clean or wipe shoes, boots and other footwear on floor mats used in the room entry process, thereby allowing contaminants into and throughout the NECC facility.

UniFirst had actual knowledge of the dangers of bacteria, mold and other microorganisms. UniFirst knew or should have known that such contaminants - if not eliminated - would expose patients and end use consumers such as Mr. Keim, to contamination of products produced by NECC in its cleanrooms. Indeed, UniFirst had actual knowledge of the very mold that was ultimately found in the NECC facility. In a "white paper" found on the www.unifirst.com website, UniFirst identifies aspergillus niger as a "mold" that grows when garments are contaminated. In the white paper, UniFirst acknowledges that this mold represents one of the most common types of microorganism contaminants found in facilities like the NECC location.

Over a significant period of time, UniFirst willfully and knowingly failed to abide by regulations, laws and guidelines, including its own policies and procedures and those of NECC, set forth to protect consumer safety in the cleaning and ongoing maintenance of NECC's facilities, including the cleanrooms. Consequently, UniFirst allowed dangerous contaminants into, and failed to eliminate these dangerous contaminants from, NECC's facilities. For instance, between January

2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the cleanroom used for the production of methylprednisolone acetate. Moreover, Aspergillus niger was found or brought into NECC's facilities. UniFirst, its agents, and employees knew or should have known of the dangers of allowing contaminants into NECC's facilities, including its anterooms and cleanrooms.

Unless UniFirst offers a reasonable settlement amount to resolve this matter, Mr. and Mrs. Keim intend to amend their complaint to add claims against UniFirst pursuant to Chapter 93A based on the facts as summarized above.

Damages

> A plaintiff who has suffered physical injury through the fault of a defendant is entitled to recover for pain and suffering; for reasonable expenses incurred by him for medical care and nursing in the treatment and cure of his injury; for diminution in his earning power; and for such pain and suffering and such expenses and diminution of earning capacity as are shown to be reasonably probable to continue in the future. The measure of damages is fair compensation for the injury sustained.

Rodgers v. Boynton, 315 Mass. 279, 280 (1943). *Accord Donovan v. Philip Morris USA, Inc.*, 455 Mass. 215, 221 (2009).

> With respect to Chapter 93A claims, the following relief is provided:
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> recovery shall be in the amount of actual damages . . . or up to three but not less than two times such amount if the court finds that the use or employment of the act or practice was a willful or knowing violation of said section two or that the refusal to grant relief upon demand was made in bad faith with knowledge or reason to know that the act or practice complained of violated said section two.

Mass. G. L. c. 93A, § 9(3). Additionally, a prevailing plaintiff is also entitled to reasonable attorneys' fees and costs pursuant to Mass. G. L. c. 93A, § 9(4).

As a consequence of being injected with the contaminated drug, Mr. Keim suffered from continued pain in his back which required surgical intervention. Following the surgery, Mr. Keim's surgeon stated that Mr. Keim had considerable scarring adhesion of the nerve root to the disk, which was not usual, and that a contaminated injection and local infection could have caused the amount of scar tissue that was present, and Mr. Keim may have some permanent injury to that nerve. Additionally, Mrs. Keim has suffered the loss of love and companionship of her husband.

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Please be advised that if UniFirst or its insurer(s) fail to respond with a good faith offer of settlement within thirty (30) days of receipt of this letter, the Court may find additional violations of Chapter 93A and award reasonable attorneys' fees and multiple damages of up to three times the actual damages found at trial. *See* Mass. G. L. c. 93A, § 9(3).

Conclusion

Pursuant to Massachusetts General Law, Chapter 93A, § 9, demand is made to UniFirst to make a reasonable offer of settlement within thirty (30) days of the date of this letter.

Regards,

PRICE WAICUKAUSKI & RILEY, LLC

William N. Riley

WNR/ema